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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/620,806 | 07/17/2003 | Sylvia Daunert | 50229-378 | 8451 |

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MCDERMOTT, WILL & EMERY
600 13th Street, N.W.
Washington, DC 20005-3096

EXAMINER

GRUN, JAMES LESLIE

| ART UNIT | PAPER NUMBER |
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1641

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12/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/620,806 | Applicant(s) DAUNERT ET AL. | |
| | Examiner James L. Grun | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 8-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 October 2007, requesting entry of the response filed 11 September 2007, is acknowledged and the responses have been entered. Claims 7 and 21 have been cancelled. Claims 1-6 and 8-20 remain in the case. Claims 1-5 and 8-20 have been withdrawn from further consideration as being drawn to a non-elected invention.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to and claim 6 is rejected under 35 U.S.C. § 112, first paragraph, for reasons similar to those of record as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, and which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant teaches a method using reagents comprising antibodies specific for 6-keto-prostaglandin $F_{1\alpha}$ (6-keto-PGF $_{1\alpha}$), a covalent conjugate of aequorin, preferably an aequorin mutant having a single cysteine residue, with 6-keto-PGF $_{1\alpha}$, and immobilized anti-immunoglobulin antibodies (see e.g. pages 13 or 15). Absent further written description and guidance from applicant one would not be assured of the ability to make and use the invention as

instantly claimed wherein 6-keto-PGF_{1α} binds to a sulfhydryl group of a “unique” cysteine residue. It is not clear in what way the cysteine residue is unique. Applicant has not described or enabled binding other than a covalent bond between the 6-keto-PGF_{1α} and mutant aequorin molecules of the conjugate via a cross-linking reaction of the carboxyl group of the 6-keto-PGF_{1α} to the sulfhydryl group of the cysteine.

Applicant's arguments filed 11 September 2007 and entered on 02 October 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

Claim 6 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 6 the interrelationships of the components are not clear, e.g. it is not known how a cysteine-free aequorin mutant comprises a cysteine residue, and it is not clear if the 6-keto-prostaglandin F_{1α} is provided in a form which binds to the sulfhydryl or already bound to the aequorin.

Applicant's arguments filed 11 September 2007 and entered on 02 October 2007 have been fully considered but they are not deemed to be persuasive. Notwithstanding applicant's assertions to the contrary, applicant's amendments have not obviated rejections under this statute for the reasons set forth above.

The examiner would suggest:

- 22. (New) A kit for measuring prostacyclin in plasma comprising:
- (1) an anti- 6-keto-prostaglandin $F_{1\alpha}$ (6-keto-PGF $_{1\alpha}$) antibody;
 - (2) an anti-immunoglobulin antibody that binds to the anti-6-keto-PGF $_{1\alpha}$ -antibody; and
 - (3) a conjugate comprising 6-keto-PGF $_{1\alpha}$ covalently bound to an aequorin mutant;
- wherein said aequorin mutant comprises serine substitutions for all three cysteine residues as present in wild-type aequorin (Cys \rightarrow Ser), wherein said aequorin mutant further comprises a single cysteine residue substituted at amino acid position 69 (Ala69 \rightarrow Cys), 70 (Gly70 \rightarrow Cys), 74 (Gly74 \rightarrow Cys) or 76 (Glu76 \rightarrow Cys), and wherein the 6-keto-PGF $_{1\alpha}$ is coupled to the aequorin mutant via reaction with the sulfhydryl group of the single cysteine. --

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone number for official facsimile transmitted communications to TC 1600, Group 1640, is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JLG/
James L. Grun, Ph.D.
December 18, 2007


LONG V. LE 12/21/07
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600